IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent application of:

Applicant(s): Dieter Grob et al.
Serial No: 10/762,008
Filing Date: January 21, 2004
Title: CERVICAL FACET RESURFACING IMPLANT
Examiner: Mary C. Hoffman
Art Unit: 3733
Docket No. HORA.P0102US

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The undersigned submits this corrected brief for the Board's consideration of the appeal of the Examiner's decision, mailed February 12, 2007, finally rejecting claims 1, 2, 4-6, 8-24 and 38-53 of the above-identified application. A payment covering the filing fee was included with the original brief filed on April 18, 2007.

I. Real Party in Interest

The real party in interest in the present appeal is **Gerraspine A.G.**, a corporation of Switzerland having a place of business at Rorschacher Str. 292, 9016 St. Gallen, Switzerland, the assignee of the present application.

II. Related Appeals and Interferences

Although the application does not claim priority from the present application or parent thereof, a notice of appeal and appeal brief have been filed for U.S. Application No. 10/651,871, which involves similar legal issues and cited art and therefore may be affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1, 2, 4-6, 8-24 and 38-53 are pending. Claims 3, 7 and 25-37 have been cancelled. Claims 1, 2, 4-6, 8-24 and 38-53 stand finally rejected and are the subject of this appeal. A correct copy of claims 1, 2, 4-6, 8-24 and 38-53 is reproduced in the Claims Appendix.

IV. Status of Amendments

Following the final rejection of claims 1, 2, 4-6, 8-24 and 38-53 in an action dated February 12, 2007, an interview was conducted with the Examiner on February 23, 2007. An amendment was then filed on February 23, 2007 in an attempt to amend claims 38-40, 42-46 and 48-53. The Examiner did not enter any of the amendments to the claims for the purposes of appeal. The Claims Appendix therefore represents the claims as finally rejected in the action mailed February 12, 2007.

V. Summary of Claimed Subject Matter[1]

The claimed subject matter relates generally to prostheses for treating spinal pathologies, and more specifically to a system and method for treating articulating surfaces of cervical facet joints. [1/8-10][2]

The Invention as Defined in the Rejected Claims

Claim 1: A cervical facet resurfacing implant comprises a superior implant (102) having an articulating surface (110) and a fixation surface (112). The superior implant is configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra. [5/30 – 6/32; 7/27 – 8/28; Figs. 5B-C, 6A-C; various shapes and features of the superior implant (102) are described throughout pages 5-12 of the specification]. The cervical facet implant also comprises an inferior implant (104, 204) having an articulating surface (118, 208) and a fixation surface (120, 210). The inferior implant (104, 204) is configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface (118, 208) of the inferior implant (104, 204) interacts with the articular surface (110) of the superior implant (102). [5/30 – 6/11; 8/9-17; 8/29 – 12/6; Figs. 5B-C, 6A-C, 7; various shapes and features of the inferior implant (104, 204) are described throughout pages 5-12 of the specification]. At least one of the superior implant (102) or the inferior implant (104, 204) comprises a tab (108, 116)

---

[1] This summary is presented in compliance with the requirements of 37 C.F.R. §41.37(c)(1)(v), mandating a concise explanation involved in the appeal. Nothing contained in this summary is intended to change the specific language of the claims described, nor is the language in the summary to be construed so as to limit the scope of the claims in any way.

[2] Page number/line number(s) of the specification.

extending from a lateral edge of the implant. [6/33 – 7/8; 9/14-23]. The tab (108, 116) has an aperture for receiving a fixation device. [7/9-12; 9/24-27].

Claim 2: The facet implant of claim 1 wherein the superior implant (102) and inferior implant (104) are each generally disk-shaped. [5/30 – 6/11].

Claim 8: The cervical facet resurfacing implant of claim 1 wherein the inferior implant comprises a tab configured for attachment to the inferior articular process of the cervical vertebra immediately above the selected cervical vertebra. [7/9-12; 9/24-27; 6A-C].

Claim 20: A facet implant comprises a generally disk-shaped superior (102) having an articulating surface (110) and a fixation surface (112). The superior implant is configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra. [5/30 – 6/32; 7/27 – 8/28; Figs. 5B-C, 6A-C; various shapes and features of the superior implant (102) are described throughout pages 5-12 of the specification]. The superior implant has a tab (108) extending from a lateral edge of the generally disk-shaped portion (106) of the superior implant (102). [6/33 – 7/8]. The tab (108) has an aperture for receiving a fixation device for secured attachment to the lateral mass of the selected vertebra. [7/9-12].

The facet implant also comprises a generally disk-shaped inferior implant (104) having an articulating surface (118) and a fixation surface (120). The inferior implant (104) is configured for placement on a resurfaced inferior articular facet of a cervical vertebra immediately above the selected cervical vertebra or occiput such that the articulating surface (118) of the inferior implant (104) interacts with the articular surface (110) of the superior implant (102). [5/30 – 6/11; 8/3-17; 8/29 – 11/8; Figs. 5B-C, 6A-

C; various shapes and features of the inferior implant (104) are described throughout pages 5-11 of the specification]. The inferior implant has a tab (116) extending from a lateral edge of the generally disk-shaped portion (114) of the inferior implant (104). [9/14-23]. The tab (116) has an aperture for receiving a fixation device for secured attachment to the inferior articular process of the cervical vertebra immediately above the selected vertebra. [9/24-27].

Claim 38: A cervical facet resurfacing implant comprises superior implant means for providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra, the superior implant means being configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the superior implant means is the superior implant (102). [5/30 – 6/32; 7/27 – 8/28; Figs. 5B-C, 6A-C; various shapes and features of the superior implant (102) are described throughout pages 5-12 of the specification].

The facet implant also comprises inferior implant means for providing an artificial articulating surface on an inferior articular facet, the inferior implant means being configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra. This element is subject to 35 U.S.C. § 112, ¶ 6. The structure that corresponds to the superior implant means is the inferior implant (104, 204). [5/30 – 6/11; 8/9-17; 8/29 – 12/6; Figs. 5B-C, 6A-C, 7; various shapes and features of the inferior implant (104, 204) are described throughout pages 5-12 of the specification]. The superior implant means and the inferior implant means are configured for articulating interaction. [6/29-32; 8/3-17].

VI. Grounds of Rejection to Be Reviewed on Appeal

A. Claims 1, 2, 8-13, 15-22, 24, 38-47 and 49-53 stand finally rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2002/0151895 (***Soboleski***).

B. Claims 1, 8-12, 14, 15, 18, 19, 38, 43-49 and 52-53 stand finally rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,571,191 (***Fitz***).

C. Claims 1, 2, 4-6, 8-15, 20-24 and 38-49 stand finally rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2004/0127989 (***Dooris***).

D. Claims 16, 17, 50 and 51 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over ***Fitz***.

E. Claims 16, 17, 50 and 51 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over ***Dooris***.

F. Claims 14, 23 and 48 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over ***Soboleski*** in view of U.S. Patent Publication 2002/0151895 (***Lee***).

VII. Argument[3]

The rejections advanced by the Examiner are improper and should be reversed for at least the following reasons.

[3] In the event the Examiner clarifies the rejections of any claims that have not been argued separately, Applicant reserves the right to argue separately such claims.

Background

Degenerative spinal diseases can involve articular surfaces only, but may also have a more invasive pathology including traumatic, infectious, tumorous or dysmorphic (spondylolisthesis, for example) effecting the destruction of all or part of the articular process. [1/32 – 2/1]. Conventional treatments generally include some type of intervertebral stabilization, which may be spinal fusion, vertebral fixation, decompressive laminectomy, or spinal disc replacement. [2/6-14]. Spinal disc replacements, for example, provide a "space" between two vertebral bodies while preserving some motion but do not function to reduce the force on posterior joint facets. [2/14-17].

These conventional treatments have varying success rates and are limited in that none puts the spine in proper alignment or return the spine to a desired anatomy. [2/18-20]. In addition, stabilization techniques permanently limit a person's mobility by holding the vertebrae in a fixed position. [2/20-22]. Indeed, even procedures utilizing motion devices not intended to limit mobility have a high incidence of spontaneous fusion. [2/20-24]. There is a need for an improved treatment for facet joint pathologies.

A. Rejection of Claims 1, 2, 8-13, 15-22, 24-47 and 49-53 under 35 U.S.C. ' 102(e) as being anticipated by *Soboleski*

Claims 1, 2, 8-13, 15-22, 24-47 and 49-53 stand finally rejected as being anticipated by ***Soboleski***. According to the examiner:

> Soboleski et al. disclose a cervical facet resurfacing implant comprising a superior implant (ref. #16) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra (paragraph [0045-461; and an inferior implant (ref. #12) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant

interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device. The superior implant and inferior implant are each generally disk-shaped. The inferior implant further comprises a tab (e.g. see FIG. 3B, ref. #52) configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. At least one of the superior implant or the inferior implant comprises a surface fixation mechanism. The surface fixation mechanism comprises at least one of at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole (paragraph [0043]). The surface fixation mechanism comprises multiple regions and wherein each of the regions has multiple ridges oriented in a different direction than the other regions (see IFG. 3c, ref. #'s 64 and 68). The articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/AIN. The inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter (paragraph [0046]). The cervical facet resurfacing implant comprises a trans-lateral mass fixation mechanism (FIG. 3E, ref. #72) for securing the inferior implant to the inferior articular facet, which comprises a fixation pin.[4]

The Examiner's rejections are improper and should be reversed.

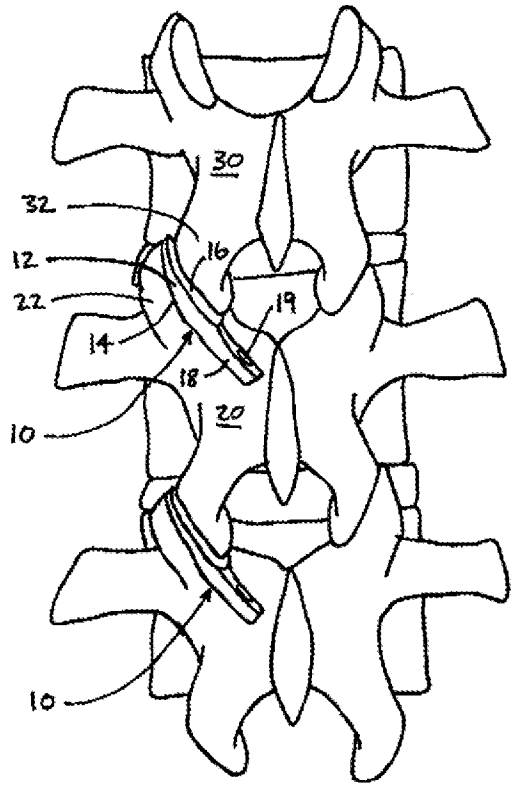
Claims 1, 2, 11-13 and 15-19

Independent claim 1 recites a facet implant comprising a superior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra; and an inferior implant having an articulating surface and a fixation surface and configured for secured

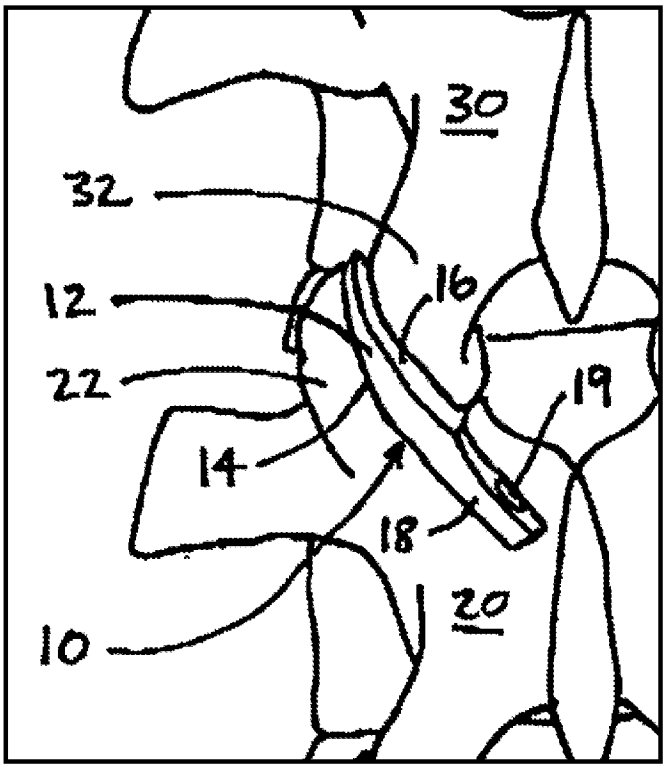
[4] Office Action dated February 12, 2007, pp. 5-6.

placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant; wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device.

Soboleski cannot anticipate independent claim 1. First, ***Soboleski*** does not disclose a cervical facet implant. There is no indication in ***Soboleski*** that the implant disclosed could even be used with cervical vertebrae. Second, ***Soboleski*** discloses only a single implant as shown below.



(Figure 2 of ***Soboleski***)



(Close-up view)

As ***Soboleski*** makes abundantly clear, the device of ***Soboleski*** is a ***single implant—not superior and inferior implants with surfaces capable of articulating with one another***. Specifically, ***Soboleski*** discloses a facet cap **10** designed to act as a shim and create space between the superior and inferior facets on one side of a vertebra to correct asymmetry and treat scoliosis. While it may appear at first glance that elements **14** and **16** of ***Soboleski*** are separate implants, ***Soboleski*** leaves no doubt that elements **14** and **16** are in fact opposing surfaces of a single implant. As described in ***Soboleski***, the facet cap **10** has a shim portion **12** with two opposing surfaces, a lower surface 14 and an upper surface 16.[5] In addition, the implant may also have an alignment portion having an extension or "tongue 18, having an orifice 19 to accept a screw or the like which is driven into the cortex of the vertebral pedicle."[6] Paragraphs 0042 and 0043 of *Soboleski* are reproduced below:

> [0042] FIG. 1 shows a posterior view of a typical scoliotic spine, with asymmetry between left and right facet joints, and spinal curvature convex left. FIG. 2 shows the spine of FIG. 1 in which the asymmetry between left and right facet joints has been corrected with two spinal facet caps according to an embodiment of the present invention. As can be seen in FIG. 2, a spinal facet cap 10 according to the invention comprises a shim portion 12 which is implanted between the superior facet 22 of a first (lower) vertebra 20 and the corresponding inferior facet 32 of a second overlying vertebra 30. The shim portion has two opposed surfaces, a first (lower) surface 14 engaging the superior articular surface of the superior facet 22, and a second (upper) surface 16 engaging the inferior articular surface of the corresponding inferior facet 32. The opposed surfaces of the shim portion of the spinal facet cap can be substantially planar, as shown in FIG. 2, or they can be formed (e.g., concave or convex) to receive and at least partially complement or parallel superior and inferior facet contours.

[5] ***Soboleski***, paragraph 0042.

[6] ***Soboleski***, paragraph 0043.

> [0043] From FIG. 2 it will be appreciated that the shim portion of the spinal facet cap must be properly aligned or positioned in the facet joint, and that this alignment must be maintained. An alignment portion is provided for this purpose. The alignment portion can be provided numerous ways in accordance with the invention. For example, the alignment portion can comprise an extension or tongue 18, having an orifice 19, to accept a screw or the like which is driven into the cortex of the vertebral pedicle. The alignment portion can also comprise one or more facet hooks and/or a ridge or boss disposed along the perimeter or margin of the shim portion, to engage the superior and/or inferior facets. The alignment portion at least partially encompasses the superior and/or inferior facet(s).

Independent claim 1 requires a superior implant and an inferior implant, each having an articulating surface configured to interact with the articulating surface of the other. ***Soboleski*** unquestionably identifies elements **14** and **16** as surfaces on opposite sides of a single implant—***not as surfaces of superior and inferior implants configured to interact with one another***:

> The shim portion has two opposed surfaces, a first (lower) surface 14 engaging the superior articular surface of the superior facet 22, and a second (upper) surface 16 engaging the inferior articular surface of the corresponding inferior facet 32.[7]

Soboleski could not be more clear. The Examiner's rejection is improper. ***Soboleski*** does not anticipate claim 1.

Claims 8-10

Claim 8 depends from claim 1. The above remarks regarding claim 1 are equally applicable to claims 8-10. Moreover, even if ***Soboleski*** were found to disclose both a superior implant and an inferior implant—which it does not—***Soboleski*** still fails to disclose an inferior implant having a tab configured for attachment to the inferior

[7] ***Soboleski***, paragraph 0042.

articular process of the cervical vertebra or occiput ***immediately above the selected cervical vertebra*** as recited in claim 8.

According to the Examiner, ***Soboleski*** includes an inferior implant having:

> A tab (e.g. see FIG. 3B, ref. #52) configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees.[8]

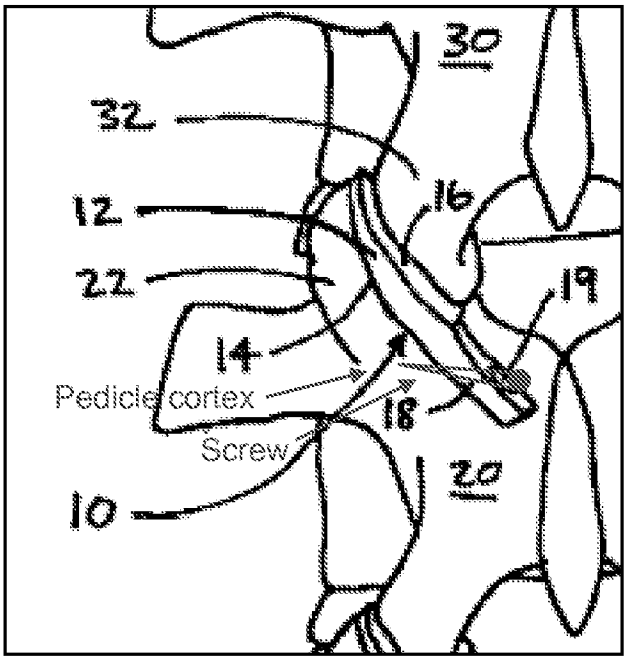
The Examiner's position lacks merit. ***Soboleski*** explains that a screw may be passed through the orifice 19 and driven into the pedicle cortex.

> For example, the alignment portion can comprise an extension or tongue 18, having an orifice 19, to accept a screw or the like which is driven into the cortex of the vertebral pedicle.[9]

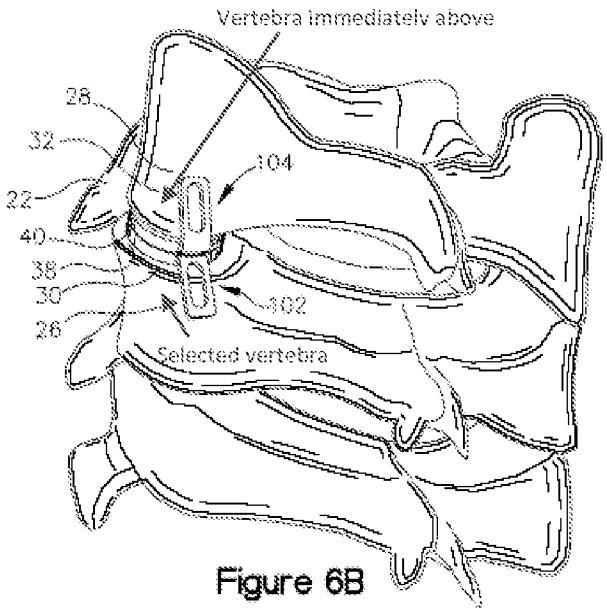
To aid in the understanding of the differences between ***Soboleski*** and the claimed invention, Fig. 2 of ***Soboleski*** is reproduced below showing how a screw would be driven into the cortex of the pedicle, which is roughly located in part along the line pointing to the cap **10**.

[8] Office Action dated February 12, 2007, p. 5.

[9] ***Soboleski***, paragraph 0043.



Soboleski with pedicle screw



Inferior implant with tab

It is clear from the images above that the pedicle cortex screw mentioned in ***Soboleski*** cannot be used to fix the implant to the vertebra immediately above the selected vertebra. It is not understood how the implant disclosed in ***Soboleski*** could be fixed to the cervical vertebra immediately above the selected cervical vertebra, and there is certainly no suggestion in ***Soboleski*** that the disclosed implant could be fixed in such a manner.

For at least the reasons above, claim 8 is not anticipated.

Claims 20-22 and 24

Claim 20 recites a facet implant comprising a generally disk-shaped superior implant having an articulating surface and a fixation surface. The superior implant is configured for placement on a resurfaced superior articular facet of a selected cervical vertebra and has a tab extending from a lateral edge of the generally disk-shaped

portion of the superior implant. The tab has an aperture for receiving a fixation device for secured attachment to the lateral mass of the selected vertebra. The facet implant also comprises a generally disk-shaped inferior implant having an articulating surface and a fixation surface. The inferior implant is configured for placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant. The inferior implant has a tab extending from a lateral edge of the generally disk-shaped portion of the inferior implant. The tab has an aperture for receiving a fixation device for secured attachment to the inferior articular process of the cervical vertebra immediately above the selected vertebra.

The above remarks regarding claims 1, 2, 11-13 and 15-19 and the remarks regarding claims 8-10 are equally applicable to claims 20-22 and 24. As is discussed above, ***Soboleski*** discloses only a single implant, not a superior implant and an inferior implant. ***Soboleski*** also fails to disclose articulating surfaces that are configured to interact with one another. Instead, ***Soboleski*** identifies elements **14** and **16** surfaces on opposite sides of a single implant. ***Soboleski*** further fails to disclose an implant, such as the claimed inferior implant that can be fixed to the cervical vertebra immediately above the selected cervical vertebra. Claim 20 is not anticipated.

Claims 38-47 and 49-53

Claim 38 recites a facet implant comprising superior implant means for providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra, the superior implant means being configured for secured placement on a

resurfaced superior articular facet of a selected cervical vertebra; and inferior implant means for providing an artificial articulating surface on an inferior articular facet, the inferior implant means being configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra; wherein the superior implant means and the inferior implant means are configured for articulating interaction.

Claim 38 invokes 35 U.S.C. § 112, ¶ 6 for the superior implant means and inferior implant means. The use of the word "implant" does not take either the superior implant means or the inferior implant means limitations out of the realm of § 112, ¶ 6. *See*, *Unidynamics Corp. v. Automatic Products Int'l, Ltd.*, 48 USPQ2d 1099 (Fed. Cir. 1998)("spring means tending to keep the door closed" is a § 112, ¶ 6 "means" clause even though it recited some structure ("spring"); *Overhead Door Corp. v. Chamberlain Group, Inc.*, 52 USPQ2d 1321 (Fed. Cir. 1999)("memory selection switch means being adapted to…." is subject to § 112, ¶ 6).

Accordingly, the structures corresponding to the means plus function elements of Claim 38 are as follows:[10]

Claim element	**Corresponding Structure**
superior implant means for providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra	superior implant (102), including the variations thereof described on pages 5-12 of the specification
inferior implant means for providing an artificial articulating surface on an inferior articular facet	inferior implant (104), including the variations thereof described on pages 5-12 of the specification

[10] Support for the corresponding structures is provided in more detail in Section V above.

As explained in more detail above, ***Soboleski*** discloses only a single implant. Soboleski does not disclose means for providing artificial ***articulating surfaces*** on both the superior articular facet and the inferior articular facet. Claim 38 is not anticipated.

B. Rejection of Claims 1, 8-12, 14, 15, 18, 19, 38, 43-49 and 52-53 under 35 U.S.C. '102(b) as being anticipated by U.S. Patent No. 5,571,191 (*Fitz*).

Claims 1, 8-12, 14, 15, 18, 19, 38 43-49 and 52-53 stand finally rejected as being anticipated by ***Fitz***. According to the examiner:

> Fitz discloses a cervical facet resurfacing implant comprising a superior implant (ref. #40) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra (col. 2, lines 20-25); and an inferior implant (ref. #50) having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab (see FIG. 3) extending from a lateral edge of the implant, and wherein the tab has an aperture (ref. #54 or 56) for receiving a fixation device. The inferior implant further comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. The inferior implant comprises a surface fixation mechanism (ref. #54 or 56). The surface fixation mechanism comprises at least one screw hole. The fixation surface of at least one of the inferior implant or the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone (col. 3, lines 35-40). The inferior implant or the superior implant is composed of Ti/AIN (col. 2, line 3). The trans-lateral mass fixation mechanism is screw (ref. #58 or 60).[11]

[11] Office Action dated February 12, 2007, pp. 2-3.

The Examiner's rejections are improper and should be reversed.

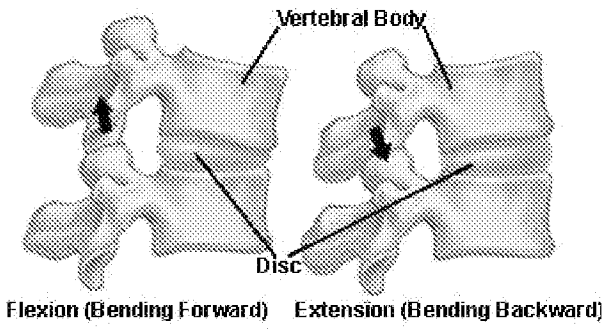
Claims 1, 8-12, 14, 15, 18 and 19

Independent claim 1 recites a facet implant comprising a superior implant having an articulating surface and a fixation surface and **configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra**; and an inferior implant having an articulating surface and a fixation surface and **configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra** or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant; wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device.

Fitz cannot anticipate independent claim 1 because Fitz is not capable of being placed on a superior articular facet of a selected cervical vertebra. Whether the phrase "configured for" introduces structural limitations in a claim depends on the specific facts of the case. See, MPEP 2111.04. In this case, the phrase "configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra" requires that the superior implant be capable of placement on a superior articular facet of a cervical vertebra. Likewise, the phrase "configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra" requires that the inferior implant be capable of placement on an inferior articular facet of a cervical vertebra. The superior and inferior implants of ***Fitz*** are not capable of such placement.

As is clearly evident from the figures below, the device of ***Fitz*** is neither appropriately dimensioned nor appropriately shaped for placement on articular facets of adjacent cervical vertebrae. Rather, ***Fitz*** is shaped for placement on articular facets of lumbar vertebrae, which are much more flexible and have much greater vertebral spacing than cervical vertebrae. Lumbar facet joint kinematics permit the use of an implant such as that described in ***Fitz***—cervical facet joint kinematics do not.

Lumbar Facet Joint



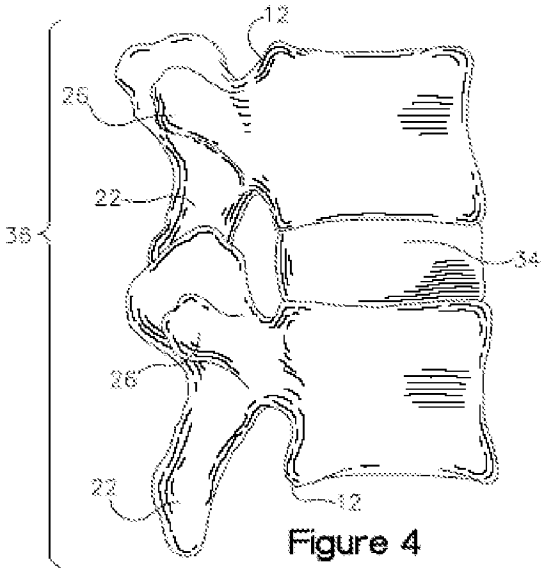
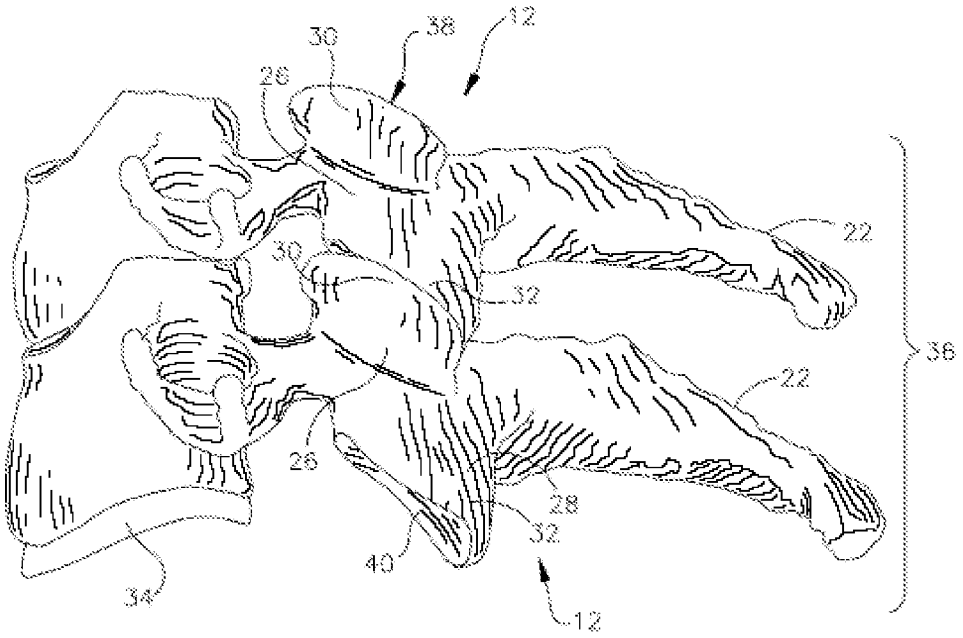


Figure 4

Cervical Facet Joint



As illustrated below, there is simply not enough space between the articular facets in a cervical facet joint to place a device such as the one described in ***Fitz***. An attempt to create a space sufficient for placement of such an implant would result in paralysis or possibly death.

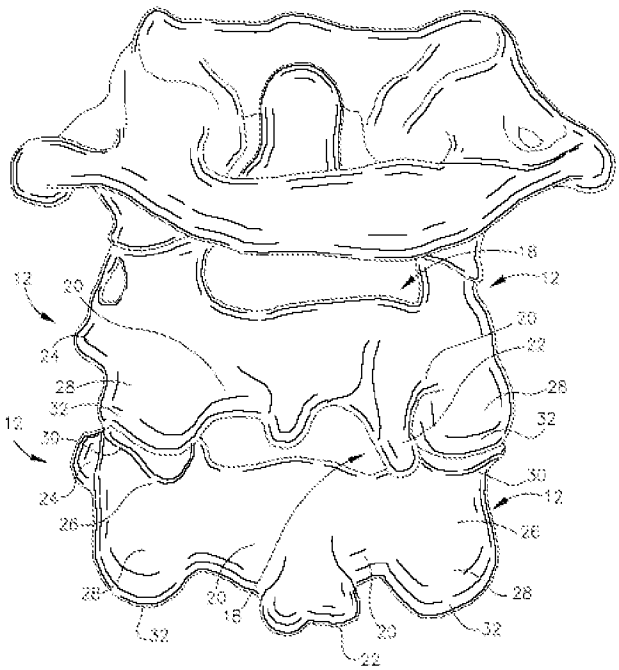
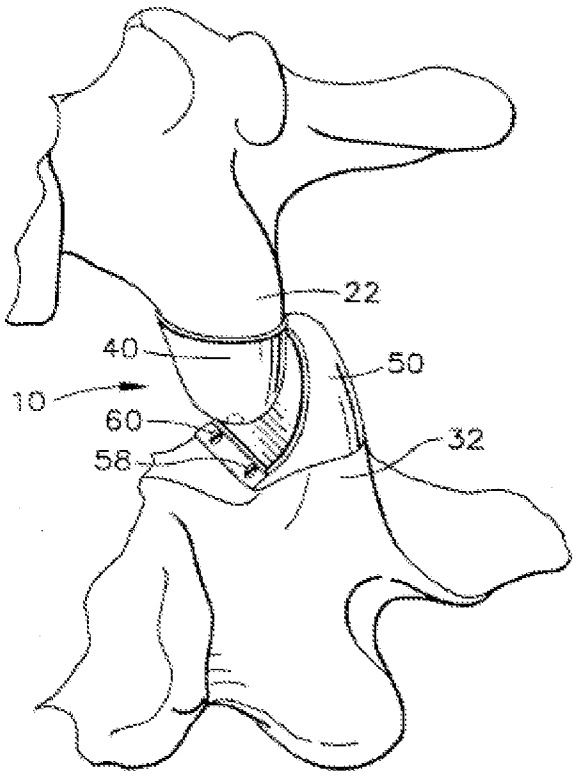


Figure 3

Cervical Vertebrae



Lumbar Vertebrae with ***Fitz*** Device
(Figure 6 of ***Fitz***)

Fitz does not disclose a device that is capable of being placed on resurfaced articular facets of cervical vertebrae. Claim 1 is not anticipated.

Claims 38, 43-49 and 52-53

As explained above with reference to ***Soboleski***, claim 38 invokes 35 U.S.C. § 112, ¶ 6 for the superior implant means and inferior implant means. The function of the superior implant means is "providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra." Similarly, the function of the inferior implant means is "providing an artificial articulating surface on an inferior articular facet."

As explained above with reference to claims 1, 8-12, 14, 15, 18 and 19, ***Fitz*** does not disclose a device that is capable of performing the function of providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra. Nor does ***Fitz*** disclose a device that is capable of performing the function of providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra. Claim 38 is not anticipated.

C. Rejection of Claims 1, 2, 4-6, 8-15, 20-24 and 38-49 under 35 U.S.C. '102(e) as being anticipated by U.S. Patent Publication 2004/0127989 (*Dooris*).

Claims 1, 2, 4-6, 8-15, 20-24 and 38-49 stand finally rejected as being anticipated by ***Dooris***. According to the examiner:

> Dooris et al. disclose a cervical facet resurfacing implant comprising a superior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra; and an inferior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device (see FIG. 11). The superior implant and inferior implant are each generally disk-shaped. The superior implant comprises a tab configured for attachment to the lateral mass of the selected cervical vertebra. The tab is configured for attachment to the lateral mass of the selected cervical vertebra with a screw. The tab extends from the remainder of the superior implant to form an angle of from about 110 degrees to about 160 degrees. The inferior implant further comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra. The tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw. The tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees. At least one of the superior implant or the inferior

implant comprises a surface fixation mechanism. The surface fixation mechanism comprises at least one of at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole (paragraph [0118]). The surface fixation mechanism comprises multiple regions and wherein each of the regions has multiple ridges oriented in a different direction than the other regions (paragraph [0118]). The fixation surface of at least one of the inferior implant or the superior implant has a material facilitating ingrowth of bone (paragraph [0059]). The articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of UHMWPE, i.e. a biocompatible material adapted for constraining but not eliminating relative movement (paragraph [0048]).[12]

The Examiner's rejections are improper and should be reversed.

Claims 1, 4-6 and 8-15

The above remarks regarding ***Fitz*** are equally applicable to ***Dooris***. ***Dooris*** does not anticipate independent claim 1. The Examiner's rejections are improper and should be reversed. As discussed in detail below, the Examiner's rejections are based on the misconception that the artificial ligament sleeve of ***Dooris*** represents two articulating implants.

The Examiner relies on Figure 11 of ***Dooris*** to support the position that ***Dooris*** discloses generally disk-shaped inferior and superior articulating implants. While it may appear at first glance that Figure 11 discloses two articulating implants, ***Dooris*** leaves no doubt that element illustrated in Figure 11 is in fact an artificial ligament sleeve attached to the inferior and superior articulating facets—not inferior and superior implants.

[12] Office Action dated February 12, 2007, pp. 3-4.

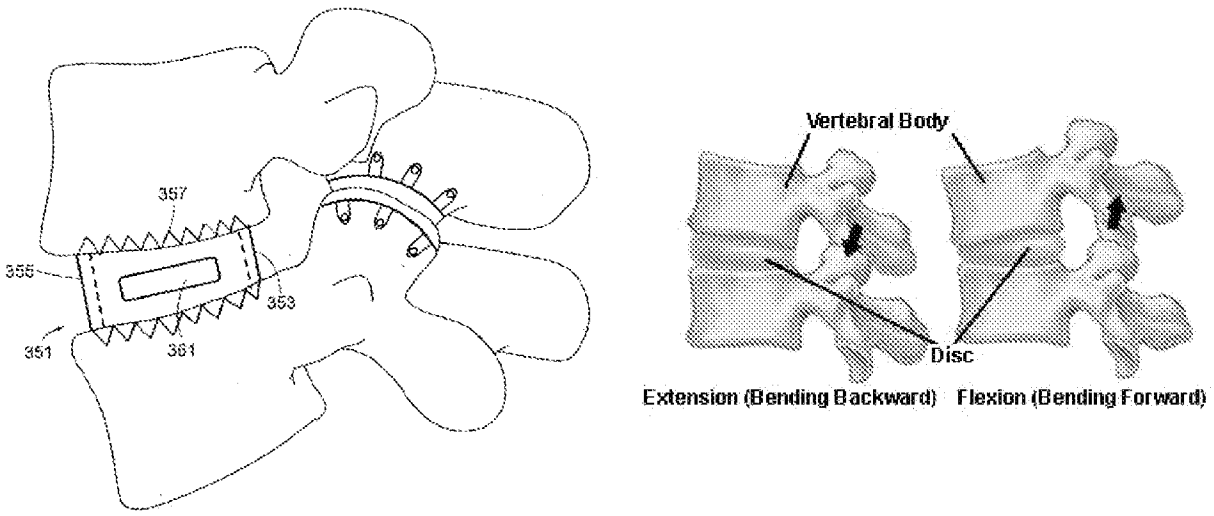


FIG. 11

The element of Figure 11 of ***Dooris*** spanning the gap between the superior and inferior articular facets of the lumbar vertebrae is unquestionably an artificial ligament sleeve. The line between the facets is merely a crease resulting from the fact that facets of the vertebrae in Figure 11 are in extension rather than in flexion. Indeed, the only description of Figure 11 in ***Dooris*** is provided below:

> **[0040] FIG. 11** discloses a pair of ***facet joint ligament of the present invention, wherein the ligament is a capsule, attached across a pair of facet joints*** of a functional spinal unit having a fusion cage inserted therein.[13]
>
> **[0140]** Now referring to **FIG. 11**, there is provided:
>
> **[0141]** a) an artificial interbody spinal fusion implant **351** for insertion within an implantation space formed across the height of a disc space between vertebral bodies of a human spine, the vertebral bodies having an anterior aspect and a posterior aspect and a depth therebetween, said implant comprising;
>
> **[0142]** a leading end **353** for insertion first into the disc space and a trailing end **355** opposite said leading end, said implant having a length from said leading end to said trailing end;

[13] Emphasis added.

[0143] a top **357** and a bottom **359** between said leading and trailing ends adapted to space apart the adjacent vertebral bodies, said top and said bottom each preferably having at least one opening **361** therethrough, said openings being in communication with one another to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant, said implant having a height H from said top to said bottom;

[0144] opposite sides between said top and said bottom, and between said leading and trailing ends, said implant having a width W from one of said sides to the other of said sides, the height of said implant preferably being less than the width of said implant;

[0145] said implant being formed at least in part of a material other than bone; and

[0146] said implant being configured to be wholly contained within the perimeter of the adjacent vertebral bodies, and

[0147] b) ***a facet joint ligament.***[14]

[0148] Preferred articulating motion devices are disclosed in U.S. Pat. Nos. 5,556,431 and 5,674,296, the specifications of which are incorporated by reference.

Figure 11 of ***Dooris*** discloses an artificial spinal fusion implant and an artificial ligament. It does not disclose superior and inferior implants with articulating surfaces and fixation surfaces. The Examiner's contention that claim 1 is anticipated by ***Dooris*** lacks merit.

Though the specific portions of ***Dooris*** were not relied on by the Examiner, ***Dooris*** does discuss facet implants. For example, ***Dooris*** discusses the use of facet implants, such as those shown in Figures 9 and 10, in conjunction with an artificial ligament.[15] None of the facet implants discussed in ***Dooris*** anticipate claim 1.

First, ***Dooris*** discloses an articulating facet joint prosthesis as illustrated in Figure 9, which is reproduced below:

---

[14] Emphasis added.

[15] ***Dooris***, ¶¶ 0113 - 0133.

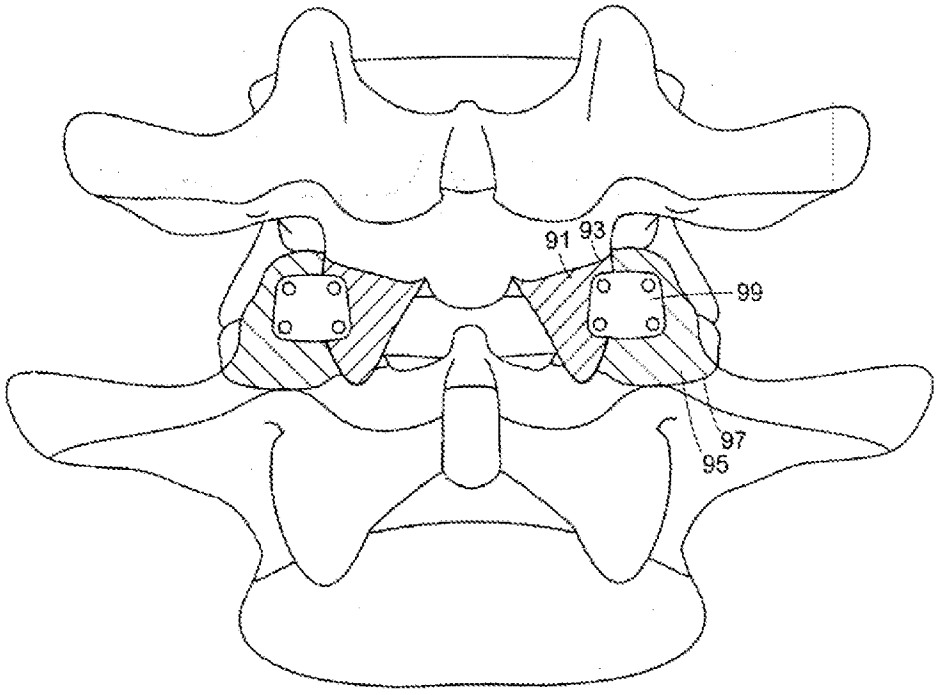


FIG. 9

Like ***Fitz***, Figure 9 of ***Dooris*** discloses an articulating lumbar facet device. The lumbar facet device includes a superior component **91** and an inferior component **95**. For the same reasons set forth above with reference to ***Fitz***, the device of Figure 9 of ***Dooris*** is not capable of being placed on resurfaced articular facets of cervical vertebrae. ***Dooris*** does not meet the limitations of claim 1. `

Dooris also discloses a non-articulating, cushion-style lumbar facet device as illustrated in Figure 10 of ***Dooris***.

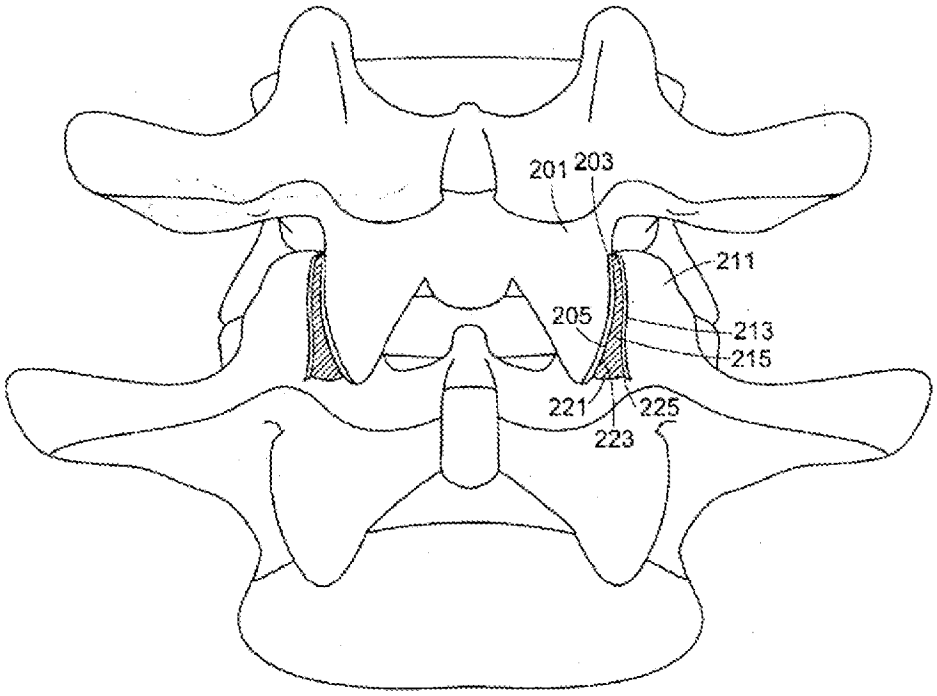


FIG. 10

The lumbar facet device includes a superior component **201** that has an outer surface **203** adapted to attach to a superior facet and an inner surface **205** attached to an elastic core **221**.[16] The lumbar facet device also includes an inferior component **211** that has an outer surface **213** adapted to attach to a superior facet and an inner surface **215** attached to the elastic core **221**.[17] For the same reasons set forth above with reference to ***Fitz*** and Figure 9 of ***Dooris***, the superior component **201** and the inferior component **211** of Figure 10 of ***Dooris*** are not capable of being placed on resurfaced articular facets of cervical vertebrae. The device of Figure 10 does not meet the limitations of claim 1.

[16] ***Dooris***, ¶¶ 0123 - 0125.

[17] ***Dooris***, ¶¶ 0124 - 0125.

In addition to the devices disclosed in Figures 9 and 10, ***Dooris*** also incorporates by reference the disclosures of U.S. Patent Nos. Re. 36,758 ("Fitz I"), 5,571,191 ("Fitz II"), 6,280,444 ("Zuchermann"), and 6,132,4464 ("Martin"). As discussed above, ***Fitz*** does not disclose a device capable of placement on resurfaced articular facets of cervical vertebrae. Like ***Fitz***, Martin and Zuchermann also disclose a devices that are incapable of being placed on resurfaced articular facets of cervical vertebrae. ***Dooris*** does not disclose any device that meets the limitations of claim 1. Claim 1 is not anticipated.

Claim 2

Claim 2 depends from claim 1 and additionally specifies that the superior implant and the inferior implant are each generally disk-shaped. According to the Examiner, Figure 11 of ***Dooris*** discloses disk-shaped superior and inferior implants:

> Dooris et al. disclose …. wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and wherein the tab has an aperture for receiving a fixation device (see FIG. 11). The superior implant and inferior implant are generally disk-shaped.[18]

As explained above with reference to claim 1, Figure 11 of ***Dooris*** does not disclose superior and inferior facet implants. Instead, Figure 11 of ***Dooris*** discloses an artificial ligament sleeve attached to the inferior and superior articulating facets. ***Dooris*** does not disclose superior and inferior disk-shaped implants. Claim 2 is not anticipated.

[18] Office Action dated February 12, 2007, pp. 3-4.

Claims 20-24

Claim 20 recites a facet implant comprising a generally disk-shaped superior implant having an articulating surface and a fixation surface. The superior implant is configured for placement on a resurfaced superior articular facet of a selected cervical vertebra and has a tab extending from a lateral edge of the generally disk-shaped portion of the superior implant. The tab has an aperture for receiving a fixation device for secured attachment to the lateral mass of the selected vertebra. The facet implant also comprises a generally disk-shaped inferior implant having an articulating surface and a fixation surface. The inferior implant is configured for placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant. The inferior implant has a tab extending from a lateral edge of the generally disk-shaped portion of the inferior implant. The tab has an aperture for receiving a fixation device for secured attachment to the inferior articular process of the cervical vertebra immediately above the selected vertebra.

The above remarks regarding claims 1, 4-6 and 8-15 and the remarks regarding claim 2 are equally applicable to claims 20-24. As is discussed above, ***Dooris*** fails to disclose a disk-shaped device that is capable of being placed on resurfaced articular facets of cervical vertebrae. Claim 20 is not anticipated.

Claims 38-49

As explained above with reference to ***Soboleski***, claim 38 invokes 35 U.S.C. § 112, ¶ 6 for the superior implant means and inferior implant means. The function of the

superior implant means is "providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra." Similarly, the function of the inferior implant means is "providing an artificial articulating surface on an inferior articular facet."

As explained above with reference to claims 1, 4-6 and 8-15, ***Dooris*** does not disclose a device that is capable of performing the function of providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra. Nor does ***Dooris*** disclose a device that is capable of performing the function of providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra. Claim 38 is not anticipated.

D. Rejection of Claims 16, 17, 50 and 51 under 35 U.S.C. ' 103(a) as being unpatentable over *Fitz*

Claims 16, 17, 50 and 51 stand finally rejected under 35 U.S.C. ' 103(a) as being unpatentable over ***Fitz***. Claims 16 and 17 depend from claim 1. The Examiner's rejection of claims 16 and 17 should be reversed for the same reasons set forth above with reference to claim 1 of ***Fitz***.

Claims 50 and 51 depend from claim 38. The Examiner's rejection of claims 50 and 51 should be reversed for the same reasons set forth above with reference to claim 38 of ***Fitz***.

E. Rejection of Claims 16, 17, 50 and 51 under 35 U.S.C. ' 103(a) as being unpatentable over *Dooris*

Claims 16, 17, 50 and 51 stand finally rejected under 35 U.S.C. ' 103(a) as being unpatentable over ***Dooris***. Claims 16 and 17 depend from claim 1. The Examiner's rejection of claims 16 and 17 should be reversed for the same reasons set forth above with reference to claim 1 of ***Dooris***.

Claims 50 and 51 depend from claim 38. The Examiner's rejection of claims 50 and 51 should be reversed for the same reasons set forth above with reference to claim 38 of ***Dooris***.

C. Rejection of Claims 14, 23 and 48 under 35 U.S.C. ' 103(a)

Claims 14, 23 and 48 stand finally rejected under 35 U.S.C. ' 103(a) as being unpatentable over ***Soboleski*** in view of ***Lee***. Claim 14 depends from claim 1. The Examiner's rejection of claim 14 should be reversed for the same reasons set forth above with reference to claim 1 of ***Soboleski***.

Claim 23 depends from claim 20. The Examiner's rejection of claim 23 should be reversed for the same reasons set forth above with reference to claim 20 of ***Soboleski***.

Claim 48 depends from claim 38. The Examiner's rejection of claim 48 should be reversed for the same reasons set forth above with reference to claim 38 of ***Soboleski***.

VIII. Conclusion

In view of the foregoing, it is respectfully submitted that the claims are patentable over the applied art and that the final rejection should be reversed.

This brief is being submitted along with a payment by credit card in the amount of $250.00 to cover the small entity fee set forth in 37 CFR 41.20(b).

Should a petition for an extension of time be necessary for the timely filing of this brief (or if such a petition has been made and an additional extension is necessary) petition is hereby made and the Commissioner is authorized to charge any fees to Deposit Account no. 18-0988, Order No. HORAP0102US.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, L.L.P.

By: /Mark C. Johnson/
Mark C. Johnson, Reg. No. 51,854

1621 Euclid Avenue, 19th Floor
Cleveland, Ohio 44115
216-621-1113

M:\H\HORA\P0102US\APPLICATION\HORA.P0102US.APPEAL BRIEF.DOC

IX. Claims Appendix

Claims on Appeal

1. A cervical facet resurfacing implant comprising:

a superior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra; and

an inferior implant having an articulating surface and a fixation surface and configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant;

wherein at least one of the superior implant or the inferior implant comprises a tab extending from a lateral edge of the implant, and

wherein the tab has an aperture for receiving a fixation device.

2. The cervical facet resurfacing implant of claim 1 wherein the superior implant and inferior implant are each generally disk-shaped.

4. The cervical facet resurfacing implant of claim 1 wherein the inferior implant comprises a tab configured for attachment to the lateral mass of the selected cervical vertebra.

5. The cervical facet resurfacing implant of claim 4 wherein the tab is configured for attachment to the lateral mass of the selected cervical vertebra with a screw.

6. The cervical facet resurfacing implant of claim 4 wherein the tab extends from the remainder of the superior implant to form an angle of from about 110 degrees to about 160 degrees.

8. The cervical facet resurfacing implant of claim 1 wherein the inferior implant comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra.

9. The cervical facet resurfacing implant of claim 8 wherein the tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw.

10. The cervical facet resurfacing implant of claim 8 wherein the tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees.

11. The cervical facet resurfacing implant of claim 1 wherein at least one of the superior implant or the inferior implant comprises a surface fixation mechanism.

12. The cervical facet resurfacing implant of claim 11 wherein the surface fixation mechanism comprises at least one of: at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole.

13. The cervical facet resurfacing implant of claim 12 wherein the surface fixation mechanism comprises multiple regions and wherein each of the regions has multiple ridges oriented in a different direction than the other regions.

14. The cervical facet resurfacing implant of claim 1 wherein the fixation surface of at least one of the inferior implant or the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone.

15. The cervical facet resurfacing implant of claim 1 wherein the articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

16. The cervical facet resurfacing implant of claim 1 wherein the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick.

17. The cervical facet resurfacing implant of claim 1 wherein the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter.

18. The cervical facet resurfacing implant of claim 1 further comprising a trans-lateral mass fixation mechanism for securing the inferior implant to the inferior articular facet.

19. The facet implant of claim 18 wherein the trans-lateral mass fixation mechanism comprises at least one of: a screw, a bolt or a fixation pin.

20. A facet implant comprising:

a generally disk-shaped superior implant having an articulating surface and a fixation surface and being configured for placement on a resurfaced superior articular facet of a selected cervical vertebra, the superior implant having a tab extending from a lateral edge of the generally disk-shaped portion of the superior implant, the tab having an aperture for receiving a fixation device for secured attachment to the lateral mass of the selected vertebra; and

a generally disk-shaped inferior implant having an articulating surface and a fixation surface and being configured for placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical vertebra such that the articulating surface of the inferior implant interacts with the articular surface of the superior implant, the inferior implant having a tab extending from a lateral edge of the generally disk-shaped portion of the inferior implant, the tab having an aperture for receiving a fixation device for secured attachment to the inferior articular process of the cervical vertebra immediately above the selected vertebra.

21. The cervical facet resurfacing implant of claim 20 wherein at least one of the superior implant or the inferior implant comprises a surface fixation mechanism.

22. The cervical facet resurfacing implant of claim 21 wherein the surface fixation mechanism comprises at least one of: at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole.

23. The cervical facet resurfacing implant of claim 20 wherein the fixation surface of at least one of the inferior implant or the superior implant has at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone.

24. The cervical facet resurfacing implant of claim 20 wherein the articulating surface of at least one of the inferior implant or the superior implant is composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

38. A cervical facet resurfacing implant comprising:

superior implant means for providing an artificial articulating surface on a superior articular facet of a selected cervical vertebra, the superior implant means being configured for secured placement on a resurfaced superior articular facet of a selected cervical vertebra; and

inferior implant means for providing an artificial articulating surface on an inferior articular facet, the inferior implant means being configured for secured placement on a resurfaced inferior articular facet of a cervical vertebra or occiput immediately above the selected cervical;

wherein the superior implant means and the inferior implant means are configured for articulating interaction.

39. The cervical facet resurfacing implant of claim 38 wherein the superior implant means and inferior implant means are each generally disk-shaped.

40. The cervical facet resurfacing implant of claim 38 wherein the superior implant means comprises a tab configured for attachment to the lateral mass of the selected cervical vertebra.

41. The cervical facet resurfacing implant of claim 40 wherein the tab is configured for attachment to the lateral mass of the selected cervical vertebra with a screw.

42. The cervical facet resurfacing implant of claim 40 wherein the tab extends from the remainder of the superior implant means to form an angle of from about 110 degrees to about 160 degrees.

43. The cervical facet resurfacing implant of claim 38 wherein the inferior implant means comprises a tab configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra.

44. The cervical facet resurfacing implant of claim 43 wherein the tab is configured for attachment to the inferior articular process of the cervical vertebra or occiput immediately above the selected cervical vertebra with a screw.

45. The cervical facet resurfacing implant of claim 43 wherein the tab extends from the remainder of the inferior implant to form an angle of from about 10 degrees to about 70 degrees.

46. The cervical facet resurfacing implant of claim 38 wherein at least one of the superior implant means or the inferior implant means comprises a surface fixation mechanism.

47. The cervical facet resurfacing implant of claim 46 wherein the surface fixation mechanism comprises at least one of: at least one peg, at least one pip, at least one fin, ridges, or at least one screw hole.

48. The cervical facet resurfacing implant of claim 38 wherein at least one of the superior implant means or the inferior implant means comprises a fixation surface having at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, or a material facilitating ingrowth of bone.

49. The cervical facet resurfacing implant of claim 38 wherein at least one of the superior implant means or the inferior implant means comprises an articulating surface composed of at least one of: cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, or Ti/Al/V.

50. The cervical facet resurfacing implant of claim 38 wherein the inferior implant means and the superior implant means each range from about 1 mm thick to about 6 mm thick.

51. The cervical facet resurfacing implant of claim 38 wherein the inferior implant means and the superior implant means each range from about 3 mm in diameter to about 14 mm in diameter.

52. The cervical facet resurfacing implant of claim 38 further comprising means for fixing the inferior implant to the inferior articulating facet.

53. The facet implant of claim 52 wherein the means for fixing the inferior implant comprises at least one of: a screw, a bolt or a fixation pin.

X. Evidence Appendix

None.

XI. Related Proceedings Appendix

None.